Central Intelligence Agency

Washington, D.C. 20505

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28 JUL 1981

Ms. Barbara Mishkin, Deputy Director
President's Commission for the Study
of Ethical Problems in Medicine and
Biomedical and Behavioral Research
2000 K Street, N.W., Suite 555
Washington, D.C. 20006

Dear Ms. Mishkin:

This is in response to your request of 17 June 1981 asking for a review of your draft summary of the Commission's report to Congress concerning the Central Intelligence Agency's policies and regulations governing research with human subjects. Your draft summary is accurate. Since the 16 June 1980 letter from the Acting Director of Central Intelligence to the Commission, the Agency has revised its regulations (appropriate portions of which are enclosed) as follows:

a. "Institutional Review Board" and "research on human subjects" are defined in accordance with the guidelines of the Department of Health and Human Services (DHHS).

b. The section "Restrictions on Experimentation" has been expanded to include the establishment of an Agency Human Subjects Research Panel (HSRP) for purposes of evaluating documentation and certification pertaining to human research conducted under Agency auspices. By this means, projects pertaining to human research may be approved, modified, or disapproved.

c. The HSRP is to provide assistance in establishing Institutional Review Boards within the Agency as described in 45 CFR 46.

With respect to the implementation of Agency policies protecting human subjects, the Director of Central Intelligence, through the HSRP, monitors Institutional Review Board (IRB) performance by requiring contractual

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assurances modeled on 45 CFR 46 to the Agency from the investigator or institution, including the general functions and operations of an IRB as therein outlined. Moreover, Agency research program managers provide continuing review at least annually (including site visits where applicable). No complaints, injuries, or departures from approved protocols have been reported or discovered in the last five years (FY 76-81).

The Central Intelligence Agency continues in its desire to be responsive and cooperative with you in carrying out the mandate of the Commission. Please feel free to call STAT [redacted], Central Intelligence Agency Liaison Officer with the President's Commission, on [redacted] STAT for further information or if he may be a further assistance.

Sincerely,

[signature]

William J. Casey
Director of Central Intelligence

Enclosure

STAT OMS [redacted] 17 July 81)
Ret [redacted] (21 July 81)

Distribution:
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(6) "Institutional Review Board" means a panel created in accordance with the requirements of 45 CFR 46 by an institution (external contractor or Agency component) conducting research on human subjects, responsible for determining whether human research subjects will be placed at risk and, if risk is involved, whether (a) the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks, (b) the rights and welfare of any such subject will be adequately protected, and (c) legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of 45 CFR 46.

(11) "Research on human subjects" means a formal investigation, designed to develop or contribute to generalizable knowledge, the subjects of which are persons about whom a scientist conducting research obtains data through intervention or interaction with the person or identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulation of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the research scientist and the subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable to fall within this definition. Data collection and analysis conducted within the limits of the normal course of approved administrative, analytical, or operational activities does not constitute research under this definition.

(k) *Restrictions on Experimentation. No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the* Department of Health and Human Services. *The subject's informed consent shall be documented as required by those guidelines.*

(1) The Director, through an Agency Human Subject Research Panel (HSRP), hereby established, shall evaluate all documentation and certification pertaining to human research sponsored by, contracted for, or conducted by the CIA (including initial and ongoing reviews conducted by Institutional Review Boards) prepared in compliance with Department of Health and Human Services guidelines, codified at 45 CFR 46. The HSRP shall be composed of such offices and employees of the CIA and such experts or consultants engaged for this purpose as the Director determines to be appropriate.

(2) On the basis of his evaluation of documentation submitted in accordance with the requirements of this regulation, the Director shall approve, require such modifications to submissions as to make them acceptable, or disapprove. With respect to approved documentation, the Director may determine the period during which approvals remain effective or otherwise condition or restrict his approval.

(3) The Agency HSRP shall disseminate procedural instructions and information necessary for the establishment and operation of Institutional Review Boards within the Agency as required by 45 CFR 46. The HSRP shall provide material to assist the components to comply with [redacted] and shall standardize information necessary for documentation and certification as required by 45 CFR 46 of institutions conducting research on human subjects.

STAT

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